Si Based Non-Leachable Novel Antimicrobial Material

“Our mission is to implement fiteBac® patented antimicrobial technology to provide a healthier world”

Dr. Yash P. Khanna - CTO
Dr. John W. Sharkey - CEO
Dr. Kirk Kinnerling - Founder

April 10, 2018
Presentation Outline

• Introduction: fiteBac® Technology
• Present Status
• Potential & Opportunities to Collaborate
• Business Model

‘the marriage of antimicrobial science with modern material technology’
Leadership of KHG fiteBac® Technology, LLC

**CEO**
John W Sharkey, Ph.D.
30 years experience in pharma and medical device space with affiliations at Novartis, Ophthalmic International, Sciele, Shionogi and Aeterna Zentaris.

**CTO**
Yash Khanna, Ph.D.
40+ years experience in the Plastics Industry with affiliations at Honeywell, Rayonier, Imerys, and Applied Minerals.

**Founder & President**
Kimmerling, DDS
Practicing dentist for over 30 years. Co-inventor of fiteBac® antimicrobial technology. Achieved FDA approval of K18 QAMS technology in dental appliances.

**CSO**
Allen Johnston, Ph.D.
Recognized expert with over 30 years experience in the design and synthesis of dental adhesive molecules with affiliations at Esstech and DM Healthcare Products.
fiteBac® Antimicrobial Technology

Patent Protected
Composition of Matter

US 9,314,407
CN 104066772B
HK 1201863

Additional applications currently under review
fiteBac® Chemistry: Step-I

- **TEOS Core**
  - Provides silicone-based framework to which functional groups may be covalently bonded to provide customized functionalities and thus capabilities

- **DC-5700**
  - Silicon Quaternary Ammonium Compound (SiQAC) with C18 ligand.
  - Ligand length proven to be most effective in conferring antimicrobial activity
  - Available in both methoxy and ethoxy versions
Basic DC-5700 Antimicrobial Additive

- Cell membrane “speared” by hydrocarbon chain, kills via lysising
- Surface-active agent, not systemic, mutation-resistant, non-harmful to host
fiteBac® Chemistry: Step-II
(Tailor-Made Functionality: Acrylate)

Acrylate functionality allows for co-polymerization within several polymer systems

- Antimicrobial does not migrate
- Wear or damage exposes fresh antimicrobial offering continuous microbiological protection
- FDA recognized as a New Molecular Entity
- FDA cleared for use in the manufacture of 510(k) dental appliances, including dentures and retainers
- Patent protection until 2032
- FiteBac® Dental LLC plans to launch
  - K18/MMA for use in manufacture of dental acrylcs in Q2/2018
  - fiteBac® Bond and fiteBac® OrthoBond in Q3/2018
Availability of fiteBac® Antimicrobial Additive

(1) Solution in EtOH
(2) Solution in MMA
(3) Free Flowing Silica Powder

H R H
O O O
C=CsSiO3SiO2(CH2)3N+C18H37Cl-
O O O
H R H

OH
\[
\begin{align*}
\text{Si} & \text{ – O – Si} & \text{ – O – Si} & \text{ – O – Si} & \text{ – O – Si} & \text{ – O – Si} & \text{ – O – Si} & \text{ – O – Si} & \text{ – O – Si} & \text{ – O – Si} \\
\text{H} & \text{R} & \text{H} & \text{H} & \text{R} & \text{H} & \text{H} & \text{R} & \text{H} & \text{H}
\end{align*}
\]
Breadth of fiteBac® Technology
1-to-4 Antimicrobial Groups

- **fiteBac® K21 Product** consists of 4 DC-5700 molecules covalently linked to a silane core
- K21 demonstrates
  - Strong adhesion to biological and polymer surfaces
  - Excellent, long term antimicrobial activity
  - Does not penetrate the skin or oral mucosa
  - Excellent penetration into exposed dentin tubules resulting in desensitization of exposed nerves
- **FDA** recognized as a **New Molecular Entity**
- Patent Protection until **2032**
- fiteBac® Dental plans to launch a 2% K21 Cavity Cleanser in **Q3/2018**
Breadth of fiteBac® Technology
Ti Core for Outstanding Flexibility

- **Core Replacement**
  - Capability to replace the inorganic Si core with Ti (TEOT), Al (TEOA) or Zr (TEOZ)
Breadth of fiteBac® Technology
Insertion into Various Polymer Systems: EPOXY Resins
### A Long Sustaining, Non-Leaching Antimicrobial
for
Most Various Polymer Systems

#### KHG fiteBac® Technology

**Organic Functional Groups and Compatible Resins Guide**

<table>
<thead>
<tr>
<th>Functional groups</th>
<th>Thermoplastic Resins</th>
<th>Thermosetting Resins</th>
<th>Elastomer-Rubber</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Polyethylene</td>
<td>Polypropylene</td>
<td>Acrylic</td>
</tr>
<tr>
<td>Epoxy</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Methacryloxy</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Vinyl</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Amino</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Isocyanate</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Mercaptane</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

---

**+++**: Very Effective
**++**: Effective

*Not all fiteBac® functional groups are capable of coupling with the resins in question*
fiteBac® K-18 Treated vs Untreated from a Single Subject

“a” = Control resin disk
“b” = 5% K18 resin disk
“green” – live fungal hyphae
“red” – dead fungal hyphae

BacLight stained CLSM merged image

fiteBac® - Validated With Peer-Reviewed Research


A Complete Listing of Relevant Papers and Reports Can be Found at
http://khgfitebac.com/research-papers-grid/
And FDA Clearance.
Clinical Data Confirms the Utility of the fiteBac® Approach

• FDA has cleared K18 QAMS for use dental acrylis
  • Lang Dental has obtained 510(k) approval for their K18 containing
    Orthodontic Acrylic 2 resin system

• In-vitro testing demonstrates polyacrylate made with K18QAMS
  inhibits adhesion of Candida albicans and reduces Streptococcus
  mutans and Actinomyces naselunii for at least 3 months.

• In a limited clinical study involving 32 patients, polyacrylate disks
  containing ~5% K18 demonstrated reduced biofilm formation versus
  disks without K18
The Benefits of fiteBac® Chemistry
Non-Leaching, Long-Acting Antibacterial, Antiviral & Antifungal Activity

Additional Benefits May Include
✓ Adhesive composition supports self-promoting adhesion to a wide variety of substrate
✓ Emulsifying properties allows previously non-miscible materials to coexist
✓ Plasticizer compatible in a variety of chemical systems
  - acrylates, epoxies, polymers, elastomers, etc
✓ Surface property modifier provides control surface energy properties
✓ Facile modifications of surface hydrophobicity or hydrophilicity
  - system dependent, user-defined
✓ Enhanced wettability and bonding onto a wide variety of substrates: carbon fibers, glass fibers, etc
✓ Promotes covalent bonding between a wide variety of filler particles and surrounding networks
✓ Bonds to silica, kaolin, aluminum trihydrate, titanium dioxide, etc.
KHG fiteBac® Technology - Limitless Applications

Dental & Oral
Antimicrobial restorations, Implants, retainers, adhesives and fillers. Treatment of oral infections (i.e. periodontal)

Medical
Antimicrobial sutures, wound care, hand sanitizer, catheters. Treatment of topical infections

Fibers and Composites
Antimicrobial clothing, carpets, tiles, etc. Filler and binder functionalization, improved wetting properties

Paints & Coatings
Antimicrobial surfaces for cleanrooms, marine applications, coating,

Petrochemical and Polymers
Antimicrobial adhesives, sheeting, films, piping. Hydrophobic surfaces, improved conversion rates, high performance materials

???
fiteBac® Business Model

- fiteBac® Skincare, LLC
  - Exclusive licensee for fiteBac® in skincare applications

- fiteBac® Dental, LLC
  - Exclusive licensee for fiteBac® in dental applications

- fiteBac® ???, LLC
  - Future licensee(s) for additional fiteBac® healthcare verticals

- KHG fiteBac® Technology, LLC
  - Holds fiteBac® IP
  - fiteBac® R&D

- Partners
  - Out-license IP for use in additional applications and products

Current

Future
CONCLUDING REMARKS

• Microbiological Issues are all around us. FiteBac® Technology, due to “Several Structural Variations” offers Uniquely Broad Opportunities in advancing the Microbiological Protection.

• fiteBac® Management is open to working with partners to create a “Healthier World”